MPD-G-MD-MA-01

Guideline for WHO-Collaborative Registration Procedure for IVDs 2026

Medical Device Section
Medical Product Division
Bhutan Food and Drug Authority

© 2026, Bhutan Food and Drug Authority, Royal Government of Bhutan
Medical Product Division
Bhutan Food and Drug Authority
Ministry of Health
Royal Government of Bhutan
P.O Box 726
Thimphu, Bhutan

List of Contributors

We would like to acknowledge following officials for their contributions in developing this guideline:

1. Ms. Kinley Penjor Tshomo , Sr. Regulatory Officer, MDS, MPD, BFDA
2. Ms. Sangay Choden , Regulatory Officer, MDS, MPD, BFDA
3. Mr. Dorji, Regulatory Officer, DES, MPD, BFDA
4. Mr. Sonam Chophel , Sr.Regulatory Officer, LVS, MPD, BFDA
5. Mr. Jigme Dorji , Sr. Regulatory Officer, DES, MPD, BFDA
6. Ms. Tenzin Wangmo , Regulatory Officer, DES, MPD, BFDA
7. Mr. Ugyen Chophel, Regulatory Officer, LVS, MPD, BFDA

Compilation and Editing

1. Mr. Tashi lepcha , Regulatory Officer, MDS, MPD, BFDA

Version History

Version	Release Date	Version history	Revised by
00	10-03-2026	Original release	See list of contributors

Table of Content

1. Introduction 1
2. Scope 1
3. Objectives 2
4. Normative references 2
5. Definitions 2
6. Acronyms 3
7. General Principle 4
8. General procedure for registration 4
9. WHO-CRP for IVDs 4
10. Document requirements 6
11. Post approval variations/changes procedure 6
12. Cancellation, suspension and withdrawal of MA granted via CRP procedure 8
13. Relevant forms 9
14. References 10
Annexure I: APPLICATION FOR REGISTRATION OF IN VITRO DIAGNOSTIC (IVD) UNDER WHO COLLABORATIVE REGISTRATION PROCEDURE (WHO-CRP) 11
Annexure II: Document requirement for CRP application 12

1. Introduction

The Medical Product Division (MPD) of the Bhutan Food and Drug Authority (BFDA) is responsible for the regulation and registration of medical products under the *Medicines Act of the Kingdom of Bhutan 2003*. As mandated in Chapter VI, Section 16.2:

> "All medicinal products manufactured, sold, distributed, and imported/exported from Bhutan must be registered under the provisions of this Act."

Accordingly, nearly all medical products approved for market access in Bhutan are registered with the BFDA. The issuance of a Marketing Authorization (MA), commonly referred to as product registration, ensures that products meet the required standards of quality, safety, and efficacy/performance which is essential for safeguarding public health and ensuring timely access to essential medical products.

As the national regulatory authority, the BFDA plays a central role in overseeing medical products but faces challenges typical of resource-limited settings, including constrained technical capacity coupled with the growing complexity of global supply chains, and timely access to essential, high-quality medical products has become more difficult.

To address these, the BFDA has adopted facilitated regulatory pathways, promoting reliance on trusted regulatory partners and international collaboration. Among these, the WHO's Collaborative Registration Procedure (CRP) allows the BFDA to leverage scientific assessments and inspection reports from the WHO Prequalification (PQ) Programme. This unredacted access, under confidentiality agreements, helps streamline the registration process, reduce duplication, and accelerate the availability of quality-assured products.

Reliance on WHO PQ outcomes enhances the efficiency and consistency of regulatory decisions while allowing the BFDA to retain full sovereign authority. All decisions remain aligned with Bhutan's national context, public health priorities, and legal framework.

Participation in the CRP strengthens collaboration with WHO, promotes regulatory convergence, and improves access to safe, effective, and high-quality medical products for the Bhutanese population.

2. Scope

2.1. This guideline shall apply to

2.1.1. Initial registration of WHO-prequalified In-Vitro Diagnostic (IVD) medical devices.

2.1.2. Any medical devices or IVDs not eligible for the WHO Collaborative Registration Procedure (WHO-CRP) shall be processed through the national registration pathways (Full or Abridged).

2.2. This guideline does not apply to:

2.2.1. other types of medical devices or health products outside the WHO-CRP framework.
2.2.2. renewal of products registered via the CRP pathway.

3. Objectives

3.1. To provide clear guidance to applicants on the compilation and submission of WHO-CRP dossiers for the purpose of obtaining marketing authorization in Bhutan.

3.2. To guide technical assessors and dossier reviewers in the assessment of IVDs submitted through the WHO-CRP pathway.

4. Normative references

4.1. Medicines Act of the Kingdom of Bhutan 2003

4.2. Bhutan Medicines Rules and Regulation 2025

4.3. Guideline for registration of medical devices

4.4. Guideline for cancellation, suspension and withdrawal of market authorisation of medical products

5. Definitions

5.1. **Act:** It refers to the Medicines Act of the Kingdom of Bhutan 2003.

5.2. **Applicant:** It refers to a person who applies for marketing authorization of a medical product to the national regulatory authority, who must be the owner of the product. The applicant may be a manufacturer or the party applying for a product certificate. After the product is registered, the applicant becomes the marketing authorization holder (MAH). [1]

5.3. **Authority:** It refers to the Bhutan Food and Drug Authority (BFDA).

5.4. **Catalog number:** The value given by the manufacturer to identify the specific medical device as it relates to its form/fit, function and process (i.e., manufacturing processes requiring differentiation for the end user).

5.5. **Collaborative Registration Procedure (CRP):** It refers to a procedure for collaboration between WHO and participating NRAs in the assessment and accelerated national registration of WHO prequalified IVDs.[2]

5.6.

5.7. **CRP dossier**: It refers to the regulatory submission package submitted to the national regulatory authority as an application for marketing authorization or for post-registration variations or post-approval changes in line with the applicable country requirements and requirements specified in the respective procedure guidelines.[1,3]

5.8. **Facilitated regulatory pathway:** It refers to a type of regulatory pathway available to NRAs, which are meant to facilitate and accelerate the regulatory

decisions and the introduction of quality-assured products, through the use of concepts of reliance and collaboration.[4]

5.9. **In Vitro Diagnostics (IVDs)**: It refers to a medical device, used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.[2,4,5]

5.10. **Manufacturer:** It refers to any natural or legal person with responsibility for the design and/or manufacture of a medical device with the intention of making the medical device available for use, under their name, whether or not such a medical device is designed and/or manufactured by that person themselves or on their behalf by another person(s).[2]

5.11. **Marketing authorization (MA)**: Also referred to as product licence or registration certificate; is a legal document issued by the NRA for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy, performance (where applicable) and quality. [6,7]

5.12. **Marketing Authorization Holder (MAH):** It refers to any person or entity that holds the legal responsibility for the product on the market by submission of the required documentation on a product that has been listed after evaluation as registered or approved. It also refers to a person or legal entity allowed to apply for a change to the MA or licence. Also referred to as the "manufacturer" or "applicant" in this document.[6]

5.13. **Medical devices:** It refers to all devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of:

5.13.1. diagnosis, prevention, monitoring, treatment or alleviation of disease;
5.13.2. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
5.13.3. investigation, replacement, modification, or support of the anatomy or of a physiological process;
5.13.4. supporting or sustaining life;
5.13.5. control of conception;
5.13.6. disinfection of medical devices; or
5.13.7. providing information by means of in-vitro examination of specimens derived from the human or animal body.[5]

5.14. **Medical product:** It refers to any product including, but not limited to, medicines, vaccines, blood and blood products and medical devices, including in-vitro diagnostics.[5,7,8]

5.15. **Performance evaluation:** It refers to an assessment and analysis of data to establish or verify the scientific validity, and the analytical and (where applicable) clinical performance of an IVD.[2,5]

5.16. **Post-Market Surveillance:** It refers to all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure for proactively collecting and reviewing experience gained from the use of devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.[5]

5.17. **Regulatory version:** It refers to the information associated with a submission for approval by a regulatory authority. The submitted version is defined by all of the documentation related to development, manufacture, and intended use, labelling and post market surveillance of the product and all the documented evidence supporting the safety and performance claims associated with that submission. If any aspect of this documentation is different in any way between the submissions to different regulatory authorities or assessment bodies (US FDA, Health Canada, a Notified Body for CE marking, etc.) it is considered to be a different regulatory version.[4,6]

5.18. **Reliance:** It refers to the act whereby a regulatory authority in one jurisdiction takes into account and gives significant weight to assessments by another regulatory authority or trusted institution or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.[1,3,5,8,9]

5.19. **Sameness:** It refers that two products have identical essential characteristics (i.e. the product being submitted to the relying authority and the product approved by the reference regulatory authority (WHO) should be essentially the same).[9]

5.20. Within the context of this procedure, the same IVD is characterised by:

5.20.1. the same product name;
5.20.2. the same regulatory version;
5.20.3. the same product code(s);
5.20.4. the same site of manufacture and quality management system; the same data on quality, safety and performance;
5.20.5. the same design, with the same components from the same suppliers; and
5.20.6. the same information, labelling and packaging, including instructions for use and intended use.[2,10]

5.21. **Quality Management System (QMS):** It refers to an appropriate infrastructure, encompassing the organizational structure, procedures, processes, resources and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality.[7,8]

6. Acronyms

6.1. **BFDA**: Bhutan Food and Drug Authority
6.2. **BMRR:** Bhutan Medicines Rules and Regulation
6.3. **CRP:** Collaborative registration procedure
6.4. **IVD:** In vitro Diagnostics
6.5. **MA** : Marketing Authorization
6.6. **MAH:** Marketing Authorization Holder
6.7. **NRA:** National regulatory authority
6.8. **PAV:** Post approval variation
6.9. **PQ:** Prequalification
6.10. **PQT**: Prequalification team
6.11. **TAT**: Turn around time
6.12. **WHO:** World Health Organization.

7. General Principle

7.1. Regulatory reliance is the core foundation of the Collaborative Registration Procedure (CRP), enabling authorities to utilize WHO Prequalification assessment and inspection reports to support accelerated national registration *(WHO, Good Reliance Practices).*[9] The CRP is built on the premise that authorities may give significant weight to WHO's evaluations while retaining full sovereignty over the final regulatory decision *(WHO, TRS 1060 — Annex 7)*.[1]

7.2. The following are the key principles of CRP:

7.2.1. **Voluntary** - A manufacturer voluntarily expresses interest in applying the procedure to facilitate national registration of its WHO-prequalified product(s). Participation by the authority is also voluntary and based on mutual agreement *(WHO-CRP-Annex 4, TRS 996-Annex 8, TRS 1060-Annex7).*[1,2,10]

7.2.2. **Confidentiality** - The authority signs a Participation Agreement and Confidentiality Undertaking with WHO, committing to the provisions and restricted use of WHO PQ assessment information. Only authorities with a signed agreement are eligible to participate in the CRP (*(WHO-CRP-Annex 4, TRS 996-Annex 8, TRS 1060-Annex7).*[1,2,10]

7.2.3. **Product sameness** - Applicants must submit **exactly the same product** as the one prequalified by WHO. Demonstrating product sameness is a mandatory prerequisite for applying the CRP and is verified during the assessment process *(WHO-CRP-Annex 4, TRS 996-Annex 8, TRS 1060-Annex7).*[1,2,10]

8. General procedure for registration

8.1. The application shall be subject to processing fees as per existing regulations and guidelines.

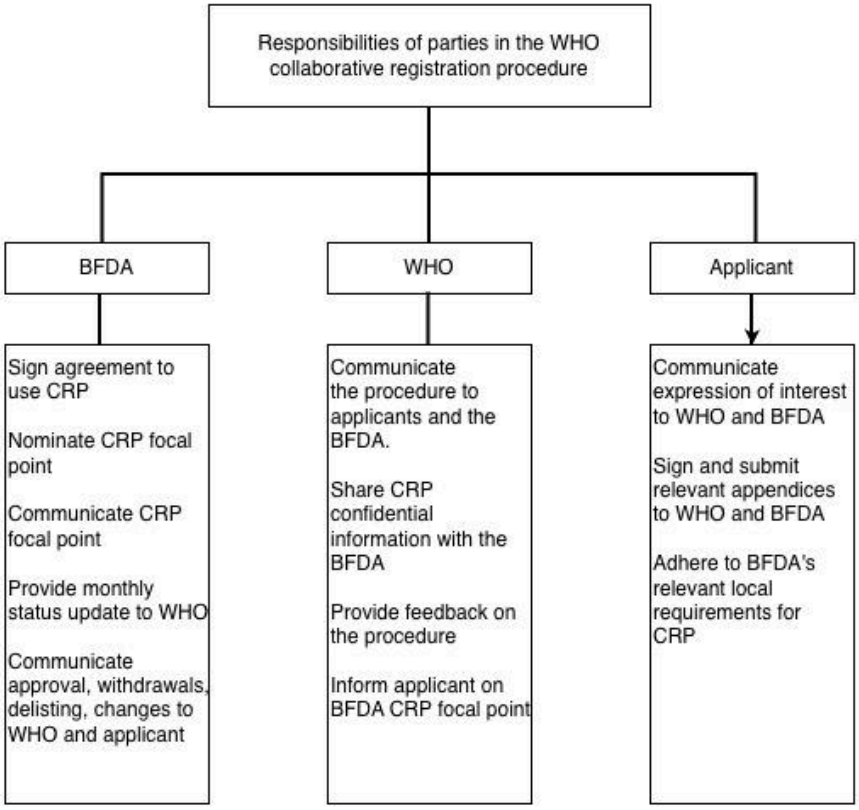
8.2. Product samples are generally not required for CRP applications. However, the authority reserves the right to request for samples on a case-by-case basis.

8.3. A maximum of two formal communication rounds shall be initiated to request clarifications or additional documentation within the TAT of **60 calendar days** of review period using the stop-clock principle.

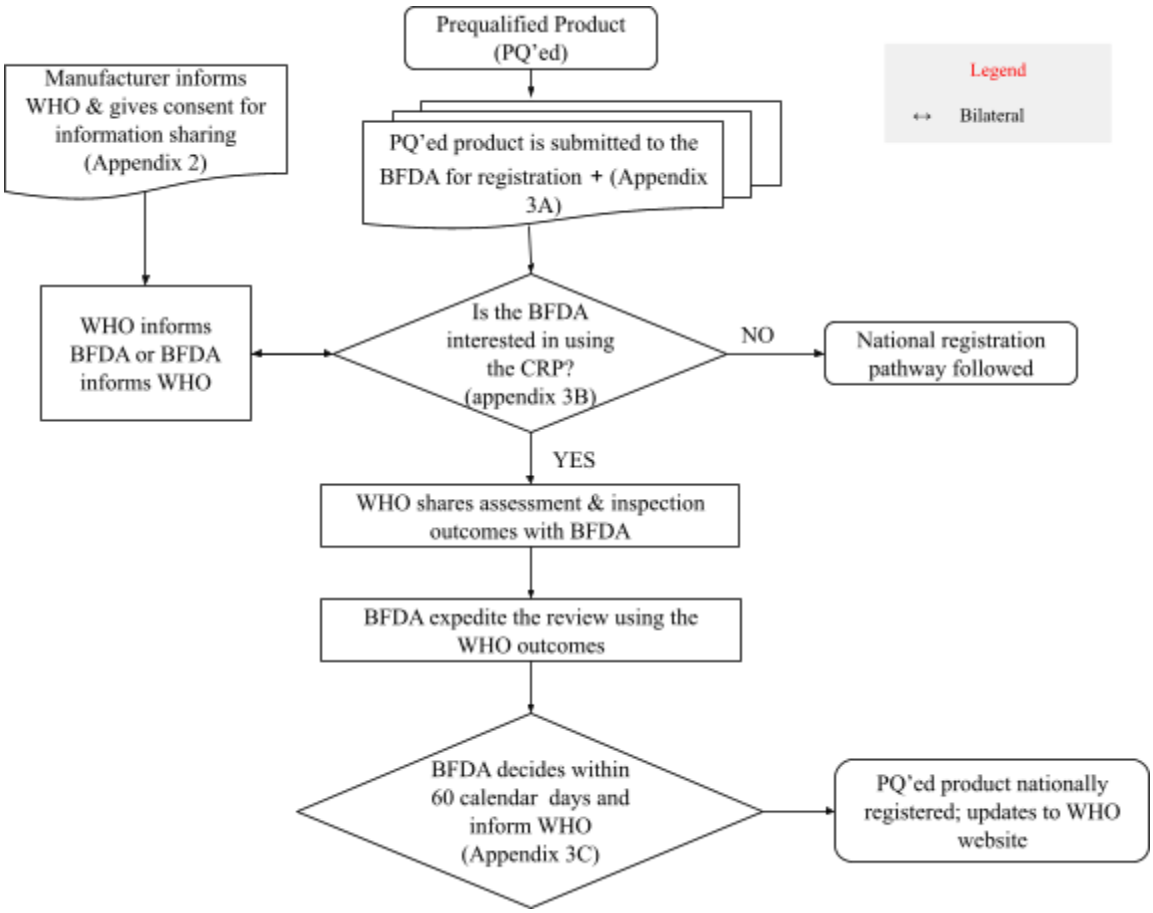
8.4. The period of submission of responses will be **6 months** from the date of communication of missing documents/clarifications. Failure to provide a complete response within a stipulated timeframe may lead to the rejection of the application.

8.5. The applicant must ensure that any post approval variations/changes to the IVD approved under the CRP are accordingly informed to WHO and the authority.

9. Responsibility of participating parties in the WHO collaborative registration procedure



10. WHO-CRP for IVDs



10.1. Process flow chart for initial registration of IVDs through CRP

Figure 1: Process flow chart for registration of IVDs through CRP

10.2. Procedure for WHO-CRP

10.3. Expression of Interest to use CRP

10.3.1. The applicant will submit the duly filled and signed ***consent form (Appendix 2)*** and ***expression of Interest (Appendix 3, Part A)*** to the WHO (crp@who.int) and the CRP focal point respectively. (OR)

10.3.2. BFDA may also inform WHO of their interest in using the CRP.

10.4. Submission of Dossier

10.4.1. Additionally, the applicant shall submit the technical dossier which should be essentially the same as the data in the dossier approved for the prequalification of the product. ***Refer to Section 10: Document Requirements.***

10.5. **Processing of CRP applications**

10.5.1. On receipt of the application, the Authority will notify the WHO and the applicant of its decision to accept or decline to apply this Procedure using ***Appendix 3: Part B.***

10.5.2. On acceptance, the WHO shares with the Authority the most recent product-related information, and dossier assessment report(s), change assessment report(s) (if applicable), manufacturing site inspection report(s), performance evaluation results, through the restricted-access website.

10.5.3. The authority will conduct the assessment of the product in question within the TAT of **60 calendar days** considering the stop clock principle. A communication of two rounds shall be provided to complete missing parts of documentation, provide additional data and/or clear any discrepancies raised by the authority.

10.5.4. The period of submission of responses will be 6 months from the date of communication of missing documents/clarifications. Failure to provide a complete response within a stipulated timeframe may lead to the rejection of the application.

10.5.5. The Authority will verify whether the product submitted for registration is the same as the product already prequalified.

10.6. **Communication of Outcome**

10.6.1. The Authority, within further **30 calendar days,** informs the applicant of its regulatory decision, and completes ***Appendix 3, Part C*** and provides it to WHO via email (crp@who.int) or restricted-access website. The appendix may be shared to the applicant as well.

11. Document format and Content

11.1. Technical Dossiers should be submitted in the same format as submitted to WHO.

11.2. The dossier should be updated to include all variations or changes approved by the WHO Prequalification Unit (where applicable)

11.3. The dossier submitted should be in English.

11.4. For any certificate or reports or authorizations in a language other than English, the product manufacturers shall be responsible for translation of such technical documents to English before submission.

11.5. Additional BFDA specific requirements should be fulfilled during the submission of the application.

11.6. The dossier content should be as per the *Annexure II.*

12. Renewal of registration

The procedure for renewal for products registered via the CRP pathway shall be subjected to the renewal procedure in place as per the current guideline for registration of medical devices.

13. Post approval variations/changes procedure

13.1. Process flow chart for Post approval variations of IVDs

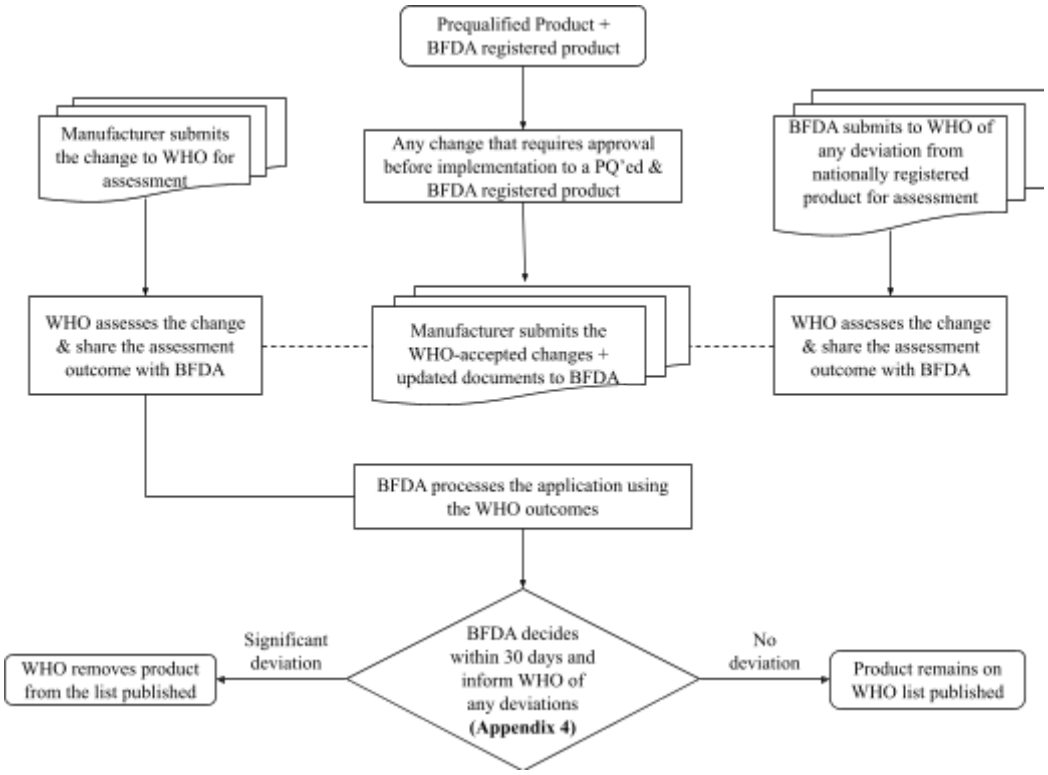


Figure 2: Process flow chart for post approval variations of IVDs

13.2. **Procedure for PAVA**

13.2.1. Post-approval variation (PAV) applications involving changes that do not impact the quality, safety, performance of the product will be accepted by the BFDA. The applicable PAV guidelines will govern the process for submitting such applications.

13.2.2. PAVs that have been approved by WHO will be considered through the Collaborative Registration Procedure (CRP), provided that the PAV dossier submitted to the authority is essentially identical to the version submitted to WHO. The submission must be accompanied by an assessment report regarding WHO PQT's acceptance of the variation.

13.2.3. Any approved PAVs for the IVD must be informed to the WHO using Appendix 4 via email (crp@who.int) or confidential restricted-access SharePoint website within 30 calendar days.

13.2.4. In cases where a national variation procedure leads to an in vitro diagnostic medical device (IVD) no longer being identical to the WHO-prequalified version, or when a variation approved by WHO is not reflected in the nationally registered product, the Bhutan Food and Drug Authority (BFDA) shall inform WHO using **Appendix 4**, with a clear description of the nature and rationale for the deviation.

13.2.5. Upon receiving notification from WHO-PQT regarding the approval of a post-approval variation (PAV), the authority shall communicate its decision—either acceptance or non-acceptance of the PAV—using **Appendix 4** within **30 calendar days**. If no response is provided within this timeframe, the variation will be deemed accepted by WHO as of the date the information was shared.

14. Cancellation, suspension and withdrawal of MA granted via CRP procedure

14.1. The Bhutan Food and Drug Authority (BFDA) shall take appropriate regulatory action in accordance with the *Guideline for Cancellation, Suspension and Withdrawal of Market Authorization of Medical Products.* This applies if a product registered through the WHO Collaborative Registration Procedure (WHO-CRP) is found to no longer be identical to the WHO-prequalified version, or if WHO delists, suspends, or withdraws the product from the Prequalification Programme.

14.2. As part of the collaborative procedure, the BFDA will maintain communication with the WHO and take decisive national action as follows:

14.3. The BFDA shall proactively report to WHO, with reasons or justification, any observed deviation or change that results in the nationally registered IVD no longer being identical to the WHO-prequalified product, or where evidence indicates a decline in its safety, quality, or performance.

14.4. Upon notification from WHO/PQT that a product has been withdrawn, suspended, or delisted under the procedure, the BFDA shall remove the product from the national registration list, notify the applicant in writing, and publish the updated status in the national register or relevant communication channel. If the action is based on safety or quality issues, the Authority will also cause the removal of that product from the market through a recall.

14.5. In addition, the applicant may voluntarily request withdrawal of a product registered under the WHO-CRP. The applicant shall notify the BFDA in writing

at least 30 calendar days prior to the intended withdrawal date, and **within 7 calendar days** if the withdrawal is due to identified safety, quality, or performance concerns. The request shall include the justification for withdrawal, details of batches on the market, and a discontinuation or recall plan where applicable. The applicant shall also notify WHO/PQT of the voluntary withdrawal using the CRP reporting form (Appendix 4).

14.6. Upon acceptance of the voluntary withdrawal, the BFDA shall remove the product from the national registration list, notify the applicant in writing, publish updates in the national register, and inform WHO/PQT of the regulatory action. Where the voluntary withdrawal is related to safety, quality, or performance issues, the BFDA shall require the applicant to implement recalls in accordance with national recall procedures.

15. Relevant forms

15.1. **Appendix 1, Part A:** Agreement to participate in the WHO Collaborative procedure between the World Health Organization and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified in vitro diagnostics https://cdn.who.int/media/docs/default-source/medicines/regulatory-updates/fpi/appendix-1-a-nra-participation-agreement-2.pdf?sfvrsn=e0dedc52_1

15.2. **Appendix 1: Part B:** Undertaking for national regulatory authority (NRA) focal point(s) https://cdn.who.int/media/docs/default-source/medicines/regulatory-updates/fpi/appendix-1-b-undertaking-for-nra.pdf?sfvrsn=e9555fa0_1

15.3. **Appendix 2**: Consent of WHO prequalification holder for WHO to confidentially share information with the NRA under the Procedure https://extranet.who.int/prequal/sites/default/files/document_files/Appendix2_TRS996_2016_Annex8.pdf

15.4. **Appendix 3, Part A:** Expression of interest to NRA in the assessment and accelerated national registration of a WHO-prequalified in vitro diagnostic https://extranet.who.int/prequal/sites/default/files/document_files/Appendix3_PartA_WHO_TRS_996_2016_Annex8.pdf

15.5. **Appendix 3, Part B:** Decision on acceptance by the NRA to apply the Procedure to a specified WHO prequalified in vitro diagnostic product and request for access to product-specific information and documentation https://cdn.who.int/media/docs/default-source/medicines/regulatory-updates/fpi/appendix-3-part-b-decision-on-acceptance.pdf?sfvrsn=172f97c7_1

15.6. **Appendix 3, Part C:** Notification of outcomes of national registration procedure by the NRA https://cdn.who.int/media/docs/default-source/medicines/regulatory-updates/fpi/appendix-3-part-c-notification-of-outcomes.pdf?sfvrsn=1424eaf8_1

15.7. **Appendix 4:** Report on post-registration actions in respect of a product registered under the Procedure https://cdn.who.int/media/docs/default-source/medicines/regulatory-updates/fpi/appendix-4-report-on-post-registration.pdf?sfvrsn=8d027932_1

16. References

1. TRs 1060 - Annex 7: Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products. Accessed November 27, 2025. https://www.who.int/publications/m/item/trs-1060---annex-7--good-practices-of-national-regulatory-authorities-in-implementing-the-collaborative-registration-procedures-for-medical-products

2. Collaborative procedure between the WHO and NRA's in the assessment and accelerated national registration of WHO-prequalified IVD's - Annex 4. Accessed November 27, 2025. https://www.who.int/publications/m/item/collaborative-procedure-between-the-who-and-nra-s-in-the-assessment-and-accelerated-national-registration-of-who-prequalified-ivd-s-annex4

3. TRS 1019 - Annex 6: Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products. Accessed November 27, 2025. https://www.who.int/publications/m/item/annex-6-trs-1019

4. 1eW.pdf. Accessed November 27, 2025. https://kyokuhp.jihs.go.jp/library/who/2017/1eW.pdf

5. WHO Global Benchmarking Tool plus Medical Devices (GBT + Medical devices) for evaluation of National Regulatory system of medical products. Accessed November 27, 2025. https://www.who.int/publications/m/item/who-global-benchmarking-tool-plus-medical-devices-(gbt---medical-devices)-for-evaluation-of-national-regulatory-system-of-medical-products

6. Glossary | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control). Accessed November 27, 2025. https://extranet.who.int/prequal/glossary-acronyms/m

7. TRS 1025 - Annex 7: Good storage and distribution practices for medical products. Accessed November 27, 2025. https://www.who.int/publications/m/item/trs-1025-annex-7

8. TRS 1033 - Annex 11: Good regulatory practices in the regulation of medical products. Accessed November 27, 2025. https://www.who.int/publications/m/item/annex-11-trs-1033

9. TRS 1033 - Annex 10: Good reliance practices in the regulation of medical products: high level principles and considerations. Accessed November 27, 2025. https://www.who.int/publications/m/item/annex-10-trs-1033

10. TRS 996 - Annex 8: Collaborative procedure between WHO Prequalification Team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines. Accessed November 27, 2025. https://www.who.int/publications/m/item/trs996-annex08-crp-pq

Annexure I: APPLICATION FOR INITIAL REGISTRATION OF IN VITRO DIAGNOSTIC (IVD) UNDER WHO COLLABORATIVE REGISTRATION PROCEDURE (WHO-CRP)

M/s ……..... hereby applies for registration of the in vitro diagnostic (IVD) specified below under the WHO Collaborative Registration Procedure (WHO-CRP) for sale/distribution in Bhutan.

Basis for CRP Application
Note: Attach all the required documents stated in the guidelines for registration of medical devices. (please tick the boxes):

☐ The IVD is WHO-prequalified and listed on the WHO PQ website.
☐ The Consent for Information Sharing (Appendix 2) has been submitted to WHO.
☐ The product submitted is identical ("same") to the WHO-prequalified version in all regulatory, technical, and quality aspects.

Product Name (both generic & brand name)	Product Code or catalogue number	Test kit contents, their product codes, including accessories (if applicable)	Manufacturer (Name, Address, Country)	WHO Product ID	Regulatory version	PQ listing Year

Specimen type:
Intended Use:

Declaration

☐ I declare that all documents and information submitted are true and accurate to the best of my knowledge and accept liability for any false or misleading information.

☐ I confirm that I have read and understood the WHO-CRP, acknowledge that non-compliance may result in rejection of the application, and undertake to comply with the Medicines Act, Regulations, and applicable standards.

☐ I consent to the BFDA sharing relevant regulatory outcomes and product information with WHO under the WHO-CRP, with such information treated as confidential except where it is in the public domain or disclosure is required by law.

Signature of applicant
(name and contact No)
Date:

Annexure II: Document requirement for CRP application

	Module	**Documentation to be provided and further details**
Module 1 -Administrative Information		

	Module	Documentation to be provided and further details
1	Application form *(Annexure I)*	As per national requirement
2	Attachments to application form: a. Appendix 3A b. Appendix 2	-**Appendix 3A:** Expression of interest to BFDA. - A copy of **Appendix 2** (Consent for information sharing) as submitted to WHO.
3	Letter of Authorization *(Annexure V of Guideline for registration of medical device)*	Letter from the manufacturer authorizing the local agent (MAH) to register and market the product in Bhutan.
4	Price structure	The price structure must reflect the following: - Price to Distributor - Price to Retailer - MRP
Module 2 - Technical Documents		
Note: All technical information provided by the applicant under the WHO-CRP must correspond to the product and data reviewed by WHO Prequalification, including any approved variations or changes. The *performance data* submitted by the applicant must be consistent with that reviewed by WHO PQ. Any inconsistency that affects reliance under the CRP may lead to non-acceptance of the application.		
1	Performance Evidence	Performance data should contain the following but not limited to: a) information on study protocol (numbers), study sites, designs, dates of the study and methodology and acceptance criteria. b) Summary of the main findings, final conclusions, and recommendations of the performance evaluation report.
2	Product information including device labeling *(As per IMDRF requirements)*	Includes the label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents. May include advertising and promotional materials as well (where applicable)

	Module	Documentation to be provided and further details
		Sample or mock-up presentation may be required for physical verification and confirmation of product sameness.

Quality Policy of Medical Product Division

"We commit to provide consistent regulatory operations with risk based planning and continual improvement in compliance with the recognized standards to meet our consumers'satisfaction and confidence"

Bhutan Food and Drug Authority
Royal Government of Bhutan
P.O 1556
Phone: 337074/337075, Fax: 33580
Email: bfda@gov.bt Website: www.bfda.gov.bt